larly in liver surgical bleeding. Caution must be taken in interpreting results given some patient differences. A head-to-head trial comparison may be necessary to confirm differences between products.

PMD80

EFFECT OF HYDROPHILIC COATING ISOTONIC TO URINE ON INFECTIONS AND COMPLICATIONS AMONG USERS OF INTERMITTENT URINARY CATHETERS

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OBJECTIVES: Infections and urethral trauma are common complications among patients using intermittent urinary catheters. The objective of this study was to investigate the effect on complications of switching to a catheter with hydrophilic coating isotonic to urine. **METHODS:** A questionnaire was sent to 694 individuals performing daily intermittent urinary catheterization in Europe and the USA. The participants were asked to report infections and complications, as well as current and previous catheter type if applicable. Only patients reporting to currently be using a catheter type with hydrophilic coating isotonic to urine were included in the study. The patients who had previously switched catheters were asked to estimate their current infections, complications and problems as much less, less, same, more or much more compared to before the switch. Wilcoxon signed rank tests were carried out to detect changes in level of consequences after switching. Analyses were performed separately for patients who switched but stayed on catheters with hydrophilic coating isotonic to urine and patients who switched from another catheter type. **RESULTS:** The initial response rate was 57% (n=391) of which 74% (n=288) were using catheters with hydrophilic coating isotonic to urine. 129 patients reported to have switched catheters, 41 (32%) stayed on the same catheter type, i.e. hydrophilic coating isotonic to urine, and 88 (68%) switched from another catheter type. Among those patients who switched from another catheter type to a catheter with hydrophilic coating isotonic to urine, an average of 15% reported more and 32% reported less infections (p=0.042), UTIs (p=0.041), complications (p=0.062) and general problems (p=0.001). The corresponding numbers for the patients who stayed on catheters with hydrophilic coating isotonic to urine were not statistically significant. **CONCLUSIONS:** This study indicates that patients performing daily intermittent catheterization can benefit from switching to a catheter with hydrophilic coating isotonic to urine.

PMD81

IS THERE UTILITY IN CLINICAL UTILITY MODELING FOR DIAGNOSTIC TECHNOLOGIES?

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OBJECTIVES: Demonstrating clinical utility is a challenge for diagnostic companies; MolDx denied 40% of CMS applications due to insufficient clinical utility data. Trials to prove clinical utility can be expensive and lengthy. Modeling can be a relatively inexpensive method in establishing clinical utility for a novel diagnostic. The objective of this study was to determine the utility of and identify requirements and hurdles for developing clinical utility models. **METHODS:** We conducted a qualitative review of 15 clinical utility models for novel diagnostics across diverse therapeutic areas and encompassing screening, diagnostic and monitoring tests. Models were assessed based on data requirements, validity of outcomes, and ability to secure reimbursement. **RESULTS:** Clinical utility depends on: (1) test performance (relative to standard of care), (2) physician practice change (confidence in test results), (3) patient compliance/behavioral change, (4) availability and proven benefits of alternative treatment course, (5) and/or reductions in adverse events. Modeling for clinical utility is most effective in areas where clear treatment protocols exist and evidence supporting the efficacy of an alternative treatment is robust. Evidence supporting practice change and patient compliance are frequently unknown, but may be informed by literature, claims analysis and/or EMR data. Modeling clinical utility is most challenging when treatment guidelines are broad and outcomes evidence is not well differentiated. **CONCLUSIONS:** Modeling is a logical first step in assessing clinical utility. It's a cost-effective way of identifying a target population and best test placement in the continuum of care through comparison of alternative strategies. Additionally, it can be useful in identifying evidence gaps and prioritizing data collection. However unless the data supporting the model is strong, it is insufficient on its own to secure reimbursement. Analysis of claims and EMR data can be an excellent data source for supporting diagnostic utility modeling.

PMD82

GEOGRAPHIC VARIATION IN DEPRESSION DIAGNOSIS AMONG MEDICARE BENEFICIARIES WITH ACUTE MYOCARDIAL INFARCTION

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OBJECTIVES: Depression treatment after acute myocardial infarction (AMI) is important to improve outcomes. Identification of geographic variation in depression diagnosis is a needed first step to understand practice variation and its outcome implications. The objective of this study was to assess the extent of geographic variation in depression diagnosis of Medicare patients after AMI. **METHODS:** A retrospective cohort of Medicare beneficiaries hospitalized with AMI during 2007-2008 (no AMI and depression diagnosis in the previous year) was included. Depression diagnosis was identified if a patient had a depression diagnosis within 30 days after AMI admission. Using driving-area-for-clinical-care (DACC) method, zip code-specific area diagnosis ratios (ADRs) were estimated as number of patients receiving a depression diagnosis divided by the sum of predicted probabilities of receiving a depression diagnosis across patients in a driving-time zip code. Linear regression yielded predicted probability estimates of each patient receiving a diagnosis based on demographics, prior comorbidities/treatments, climate, and neighborhood characteristics. Maps were created to contrast geographic variation in depression diagnosis based on ADRs. Overall healthcare utilization was measured by Medicare spending using Dartmouth Atlas of Health Care online data. **RESULTS:** Among the 155,841 patients, 5.9% had a depression diagnosis within 30 days after AMI admission. DACC-based ADRs captured considerable variation in depression diagnosis (IQR: 0.74 – 1.21) and relatively low and high zip code-level ADRs were dispersed across the United States. ADRs for depression diagnosis were statistically significantly related to Medicare spending (Pearson correlation coefficient = 0.14, $p < 0.01$), but not local physician supply. **CONCLUSIONS:** Substantial geographic variation in depression diagnosis exists across the United States. Areas with higher general healthcare spending were more likely to have higher depression diagnosis rates. Further research is needed to explore if geographic variation in diagnosis affect health and economic outcomes to address whether depression was correctly, over- or under-diagnosed.

DISEASE-SPECIFIC STUDIES

DIABETES/ENDOCRINE DISORDERS – Clinical Outcomes Studies

PDB1

URINARY TRACT INFECTION AMONG THE SGLT 2 INHIBITORS: A META-ANALYSIS OF 19 RANDOMIZED CONTROLLED TRIALS

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OBJECTIVES: The goal of this meta-analysis was to determine if within the sodium- glucose cotransporter 2 (SGLT 2) inhibitors class, any individual drug increases the risk of urinary tract infection (UTI). **METHODS:** Data base search was conducted using Medline, PubMed, and Google Scholar. Study included trials of FDA approved SGLT 2 inhibitors canagliflozin, dapagliflozin and empagliflozin. To ensure internal validity of the selected studies, only randomized controlled trials which included patients with diabetes were included. Any trials with any special groups of patients, for example, patients with cardiovascular disease were excluded. Non-randomized trials, case reports, editorials, letters to the editors, and studies with no comparison group were excluded. Trials which did not report UTI as a side effect were excluded. A meta-analysis was conducted and data was pooled using odds ratio and 95% confidence intervals. All analysis was performed using SAS version 9.4. **RESULTS:** When the three drugs were compared, there was no significant difference in odds of developing a UTI. Sensitivity analyses were performed by excluding, in turn, the contribution of each study to the meta-analysis data. There was no significant difference in the results. **CONCLUSIONS:** Although the study reinforced the finding that urinary tract infection is one of the major adverse events caused by this class of antidiabetic drugs, this meta-analysis suggested that there was no significant difference in risk of UTIs among the three SGLT 2 inhibitors on the market.

PDB2

STUDY OF PATIENT RELATED OUTCOMES OF TYPE 2 DIABETES AND COMPARATIVE ANALYSIS OF PIOGLITAZONE SALES PRE AND POST BAN IN MUMBAI,INDIA

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INTRODUCTION: Diabetes mellitus is the leading disorder in India. Thiazolidinediones have been marketed since 1997 and are effective glucose lowering drugs, but individual drugs of this category like Pioglitazone have been linked to serious side effects like bladder cancer and hence banned in India. **OBJECTIVES:** A survey was conducted to evaluate the prescription trends of type II diabetes in Mumbai, India and the adverse drug reactions associated with it. To evaluate the effect of sales of pioglitazone after its ban was removed. To observe the variation in prescription trends as compared to normal trends in case of drug resistance. **METHODS:** Two sets of questionnaires were prepared which captured patient demographics, prescription trends and adverse drug reactions of type II diabetes patients in Mumbai, India.The questionnaires targeted 75 drug stores, 40 General Practitioners and 3 government hospitals. **RESULTS:** Average number of prescriptions received by the pharmacist under the survey were 30-40 per week. Males are more affected than females. The trend of prescriptions prescribed by the general practitioners is similar to that of prescriptions received by the drug stores. Metformin is majorly prescribed followed by Glimepiride, Voglibose, Pioglitazone. Contrasting results were obtained with respect to Pioglitazone on comparing the prescription trends of doctors to the pharmacists as it was often prescribed by doctors after its ban was removed but its sales had not increased. The most number of adverse reactions were shown by Metformin and Glimepiride followed by Pioglitazone,Gliptins and Incretin Mimetics showed minimum side effects. **CONCLUSIONS:** From our results it was observed that there was no increase in the sales of Pioglitazone. Patients were treated with Metformin and Metformin-Glimepiride combination as first line treatment. Pioglitazone and insulin are most commonly prescribed in case of a drug resistance. Dose variations were suggested by general practitioners in case of a drug resistance.

PDB3

COMPARATIVE OUTCOMES OF TESTOSTERONE THERAPY VERSUS NO TREATMENT IN HYPOGONADIC MEN

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OBJECTIVES: Testosterone therapy for the treatment of hypogonadism in older men is controversial. Previous studies on benefits have been inconclusive and there is the belief that the known potential for negative cardiac outcomes outweighs any benefit. We used a sample of Medicare patients to test the time from diagnosis of hypogonadism to positive and negative events related to treating hypogonadism **METHODS:** Using a 5% random sample of Medicare LDS claims